JUN 15 2006

K060237

CMB Antimicrobial Dressing

510(K) Summary of Safety and Effectiveness

510(k) Summary of Safety & Effectiveness	The CMB Antimicrobial Dressing is an effective barrier to bacterial penetration. It is intended for professional use only. The dressing is for use on moderately to heavily exuding partial and full-thickness wounds including decubitus ulcers, venous stasis ulcers, surgical wounds, first- and second-degree burns, grafts and donor sites.	
	New Device Name:	CMB Antimicrobial Dressing
	Predicate Device Names:	Acticoat Antimicrobial Dressing (K955453) Hydrocolloid with Zinc Wound Dressing (K973855) Absorbent Antimicrobial Wound Dressing (K033814)
Device Description	The CMB Antimicrobial dressing is a single layer dressing consisting of a woven adsorbent polyester containing elemental silver and zinc. In the presence of exudate, the dressing can be used with an appropriate secondary barrier to help maintain a moist wound healing environment.	
Intended Use	As an antimicrobial barrier, place over partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns and donor and recipient graft sites.	
Indications Statement	The CMB Antimicrobial Dressing is indicated for professional use only as an antimicrobial barrier for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns and donor and recipient graft sites.	
Technological Characteristics	Technologically, the CMB Antimicrobial Dressing and predicate devices are the similar in that they all contain a fabric/gauze/pad component and an antimicrobial component. The difference is that two antimicrobial components, silver and zinc, are included in the CMB dressing.	

Performance Data	Antimicrobial performance was tested in vitro. Biocompatibility tests performed on the CMB Antimicrobial Dressing included cytotoxicity, irritation, sensitization, pyrogenicity and systemic injection. An independent laboratory performed the testing and test results are on file.
Conclusions	Based on the 510(k) summaries and the 510(k) statements (21 CFR 807) and the information and performance data provided herein, we conclude that the CMB Antimicrobial Dressing is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
Contact	Debbie Koeneman, M.S. Silverleaf Medical Products, Inc. 1100 E. University Drive, Suite 101 Tempe, AZ 85281
Date	June 1, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2006

Silverleaf Medical Products, Inc.
% Ms. Debbie Koeneman, M.S.
Director, Regulatory Affairs
1100 E. University, Suite 101
Tempe, Arizona 85281

Re: K060237
Trade/Device Name: CMB Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 2, 2006
Received: June 5, 2006

Dear Ms. Koeneman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

510(k) Number (if known): K060237

Device Name: CMB Antimicrobial Dressing

Indications for Use:

The CMB Antimicrobial Dressing is indicated for professional use as an antimicrobial barrier for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns and donor and recipient graft sites.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The- Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K060237